

§ 520.445

by or on the order of a licensed veterinarian.

[44 FR 16009, Mar. 16, 1979]

§ 520.445 Chlortetracycline oral dosage forms.

§ 520.445a Chlortetracycline bisulfate/sulfamethazine bisulfate soluble powder.

(a) *Specifications.* Each pound contains chlortetracycline bisulfate equivalent to 102.4 grams of chlortetracycline hydrochloride with sulfamethazine bisulfate equivalent to 102.4 grams of sulfamethazine.

(b) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.150 and 556.670 of this chapter.

(d) *Conditions of use.* *Swine*—Used in drinking water as follows:

(1) *Amount.* 250 milligrams of chlortetracycline with 250 milligrams of sulfamethazine per gallon.

(2) *Indications for use.* Prevention and treatment of bacterial enteritis; aid in the reduction of the incidence of cervical abscesses; aid in the maintenance of weight gains in the presence of bacterial enteritis and atrophic rhinitis.

(3) *Limitations.* Not to be used for more than 28 consecutive days; withdraw 15 days before slaughter; as sole source of chlortetracycline and sulfonamide.

[57 FR 37323, Aug. 18, 1992]

§ 520.445b Chlortetracycline powder (chlortetracycline hydrochloride or chlortetracycline bisulfate).

(a) *Specifications.* Chlortetracycline powder contains not less than 15 milligrams per gram chlortetracycline hydrochloride, or chlortetracycline bisulfate equivalent to 25.6, 64 or 102.4 grams per pound (56.4, 141 or 225.6 milligrams per gram) chlortetracycline hydrochloride.

(b) *Sponsors.* See No. 053389 in § 510.600(c) of this chapter for conditions of use as in paragraphs (d)(1)(i)(A) and (d)(2)(i)(A) of this section; No. 010042 for conditions of use as in paragraph (d)(4) of this section; No. 000010 for conditions of use as in paragraphs (d)(4)(i)(A) and (B) and (d)(4)(ii) through (iv) of this section; Nos. 017519 and 059130 for conditions of use as in

21 CFR Ch. I (4–1–01 Edition)

paragraphs (d)(4)(i)(A) and (B) and (d)(4)(ii) and (iii) of this section.

(c) *Related tolerances.* See § 556.150 of this chapter.

(d) *Conditions of use.* (1) Use as chlortetracycline hydrochloride in drinking water as follows:

(i) *Swine*—(A) *Amount.* Ten milligrams per pound of body weight daily in divided doses.

(1) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae* (*Hemophilus* spp.), and *Klebsiella* spp.

(2) *Limitations.* Prepare a fresh solution twice daily; as sole source of chlortetracycline; administer for not more than 5 days.

(B) [Reserved]

(ii) [Reserved]

(2) Use as chlortetracycline hydrochloride in a drench or drinking water as follows:

(i) *Calves*—(A) *Amount.* Ten milligrams per pound of body weight daily in divided doses.

(1) Control and treatment of bacterial enteritis (scours) caused by *E. coli* and bacterial pneumonia (shipping fever) associated with *Pasteurella* spp., *A. pleuropneumoniae* (*Hemophilus* spp.), and *Klebsiella* spp.

(2) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; administer for not more than 5 days; do not slaughter animals for food within 24 hours of treatment; do not administer this product with milk or milk replacers; administer 1 hour before or 2 hours after feeding milk or milk replacers; a withdrawal period has not been established in prerinuating calves; do not use in calves to be processed for veal.

(B) [Reserved]

(ii) [Reserved]

(3) [Reserved]

(4) The following uses of chlortetracycline hydrochloride or chlortetracycline bisulfate in drinking water or drench were reviewed by the National Academy of Sciences/National Research Council (NAS/NRC) and found effective:

(i) *Chickens*—(A) *Amount.* 200 to 400 milligrams per gallon.